

**Department of Health and Human Services  
Substance Abuse and Mental Health Services Administration  
Center for Substance Abuse Prevention**

**Urine Specimen Collection Handbook  
for  
Federal Agency Workplace Drug Testing Programs**

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**Note: This manual applies to federal agency drug testing programs that come under Executive Order 12564 dated September 15, 1986, section 503 of Public Law 100-71, 5 U.S.C. section 7301 note dated July 11, 1987, and the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (82 FR 7920) dated January 23, 2017 (effective October 1, 2017).**

**This manual does not apply to specimens submitted for testing under U.S. Department of Transportation (DOT) Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR Part 40).**

**Previous Versions of this Handbook are Obsolete**

## Table of Contents

Introduction .....	i
Chapter 1. The Collector .....	1
Chapter 2. Collector/Collection Site Records .....	4
Chapter 3. The Collection Site .....	4
Chapter 4. Federal Agency Blind Samples.....	6
Chapter 5. The Federal Drug Testing Custody and Control Form (Federal CCF).....	7
A. Acceptable Formats for a Federal CCF.....	7
B. Federal CCF Problems .....	9
C. Federal CCF Content Requirements.....	11
D. Federal CCF Instructions for Use with Urine Collections.....	12
E. Federal CCF Distribution .....	15
Chapter 6. Verification of Donor Identity.....	16
Chapter 7. Urine Specimen Collection .....	17
A. Collection Site Security .....	17
B. Collection Supplies .....	17
C. Collection Procedure .....	19
Chapter 8. Miscellaneous Collection Issues .....	28
A. Direct Observed Collection .....	28
B. Monitored Collection .....	29
C. Inability to Provide a Sufficient Specimen .....	30
D. Donor Conduct .....	32
E. Multiple Collectors for a Specimen Collection .....	33
F. Refusal to Test .....	33
G. Problems with Specimen Bottle Labels/Seals .....	34
Chapter 9. Collector Errors and Corrective Actions .....	35

### Appendices

- Appendix A: Federal CCF Decision Trees for Collectors
- Appendix B: Direct Observed Collection Procedure
- Appendix C: Two Specimens from the Same Collection Event
- Appendix D: Insufficient Specimen

## Introduction

The Substance Abuse and Mental Health Services Administration (SAMHSA) within the U.S. Department of Health and Human Services (HHS) establishes the scientific and technical guidelines to be used by U.S. federal agencies and drug testing facilities for federally regulated drug testing. Testing must be performed at facilities certified by SAMHSA under the National Laboratory Certification Program (NLCP). HHS has maintained oversight of federally regulated drug testing through this program since it began in 1988. SAMHSA certifies two types of test facilities: laboratories and instrumented initial test facilities (IITFs). IITFs are allowed only for urine testing, and perform only the initial tests for those specimens.

The **HHS Urine Specimen Collection Handbook** provides information and guidance for the collection of urine specimens for federal agency workplace drug testing programs, based on the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG).<sup>1</sup>

The **HHS Oral Fluid Specimen Collection Handbook** provides information and guidance for the collection of oral fluid specimens for federal agency workplace drug testing programs, based on the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG).<sup>2</sup>

All federally regulated oral fluid specimens must be sent to an HHS-certified laboratory for testing. IITFs are not allowed to test oral fluid specimens.

This document and additional specimen collection resources are available on the SAMHSA website: <https://www.samhsa.gov/workplace/resources>.

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<sup>1</sup> Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine, Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, 82 FR 7920, effective 10/01/2017.

<sup>2</sup> Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid, Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, 84 FR 57554, effective 01/01/2020.

## Chapter 1. The Collector

A collector is the person trained to instruct and assist a donor in providing a specimen.

### The following restrictions apply:

1. The immediate supervisor of an employee may only collect that donor's specimen when no other collector is available. A supervisor serving as a collector must be a trained collector. The supervisor must maintain an explanatory memorandum to explain why they collected their employee's specimen.
2. The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available. A hiring official serving as a collector must be a trained collector. The hiring official should maintain an explanatory memorandum to explain why they collected the applicant's specimen.
3. A coworker who is in the same testing pool or who works with an employee on a daily basis must not serve as a collector when that employee is tested.
4. An applicant or employee must not serve as the collector by collecting their own specimen.
5. An individual working for an HHS-certified test facility may not serve as a collector if that individual can link the donor with the specimen drug test result or the report from the test facility.
6. An individual who has a personal relationship with the employee (e.g., spouse, ex-spouse, relative, close personal friend) must not serve as the collector.

### To qualify as a urine specimen collector for a federal agency program, an individual must:

1. Be knowledgeable of the collection procedure described in the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG).
2. Be knowledgeable of any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by HHS relating to the collection procedure described in the UrMG.
3. Receive training from a qualified trainer for urine specimen collectors on the following topics:
  - a. All steps to correctly perform a urine specimen collection in accordance with this Specimen Collection Handbook.
  - b. Completion and distribution of the Federal Custody and Control Form (CCF). (See **Note** below.)
  - c. Problem collections.
  - d. Fatal and correctable flaws and how to correct problems during collections.

- e. Collector responsibilities to maintain the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.
4. Demonstrate proficiency in urine collections by successfully completing five consecutive error-free mock collections that include: one uneventful scenario, one insufficient specimen quantity scenario, one temperature out of range scenario, one scenario in which the donor refuses to sign the Federal CCF and one scenario in which the donor refuses to initial the specimen bottle tamper-evident bottle seal.
    - a. The qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are error-free.
  5. Document their completed training as a collector in accordance with the above requirements before collecting any specimens for a federal agency.
  6. Maintain training documentation and provide it to a federal agency upon request.

**Note:** The collector training outlined above must be conducted using a paper Federal CCF. To use an electronic Federal CCF (ECCF) for oral fluid collections, a trained collector must complete separate additional training from the ECCF system provider. That training should address use of the ECCF system for uneventful collections as well as problems that may arise during an ECCF collection including, but not limited to, a donor's refusal to test, a printer problem, insufficient specimen, and a donor's refusal to sign the CCF. See also ECCF definitions and requirements in **Chapter 5, Section A**.

**A trained urine specimen collector must:**

1. At least every five years from the date of initial training, complete refresher training that includes all initial training items (items 1-5 above).
2. Document training in accordance with the above requirements before collecting any federal agency specimens more than five years after initial training.
3. Maintain training documentation and provide it to a federal agency upon request.

**To qualify as an observer for a direct observed urine specimen collection for a federal agency program, an individual must:**

1. Be knowledgeable about the direct observed collection procedure as described in the UrMG.
2. Be knowledgeable about any guidance provided by the federal agency or by HHS relating to the direct observed collection procedure described in the UrMG.
3. Receive training on the following subjects:
  - a. All steps necessary to perform a direct observed collection.
  - b. The observer's responsibility for maintaining the integrity of the collection process.

- c. Ensuring the security of the specimen throughout the collection process by maintaining visual contact with the collection container until it is delivered to the collector.
  - d. Ensuring the privacy of the donor being tested.
  - e. Ensuring that the observation is done in a professional manner, to minimize the discomfort to the donor.
  - f. Avoiding conduct or statements that can be viewed or interpreted as offensive or inappropriate.
4. Be the same gender as the donor's gender, as determined by the donor's gender identity. There are no exceptions to this requirement. **Note:** The donor's gender identity may be the same as or different from the donor's sex assigned at birth.
  5. An observer is not required to be a trained collector.

**To qualify as a trainer for urine collectors for a federal agency program, an individual must:**

1. Be qualified as a trained collector and have regularly conducted urine drug test collections for a period of at least one year OR have successfully completed a "train the trainer" course given by an organization (e.g., manufacturer, private entity, contractor, or federal agency).
2. Complete refresher training in accordance with collector requirements (see above) at least every five years from the date of the individual's initial training.
3. Maintain records documenting trainer qualification (e.g., original records for initial and refresher collector training, "train the trainer" course certificate, employment records) and provide copies to a federal agency or to a federal agency's Medical Review Officer (MRO) upon request.

**Before a collector is permitted to collect a urine specimen for a federal agency, the agency must:**

1. Ensure that the collector has satisfied the urine specimen collector requirements described in the UrMG.
2. Ensure that the collector, who may be self-employed, or an organization (e.g., third party administrator that provides a collection service, collector training organization, federal agency that employs its own collectors) maintains a copy of the collector's training documentation.
3. Provide the collector with the name and telephone number of the federal agency's designated representative.

The collector should have identification with their name and their employer's name, address, and telephone number. The collector is required to provide their identification (employee badge

or employee list) if requested by the donor. There is no requirement for the collector to have identification (ID) with their photo or to provide their driver's license with an address.

## **Chapter 2. Collector/Collection Site Records**

The collector must maintain their original collector training records (i.e., for initial, additional, and refresher training) and provide copies to their employer and, as requested, to the federal agency.

Collection site records must be stored at a secure site designated by the collector or the collector's employer for a minimum of two years. Collection site records include the collector copies of the Office of Management and Budget-approved Federal CCF for each specimen. Both hardcopy and electronic collection records must be stored and disposed of in a manner that ensures donor confidentiality is maintained. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Personally identifiable information (PII) is information that can be used to distinguish or trace an individual's identity alone or when combined with other personal identifying information which is linked or linkable to a specific individual. PII that may be on the Federal CCF includes the donor's Social Security Number (SSN), name, date of birth, telephone numbers, and employment status. All federally regulated employers and drug testing service providers (including collectors) must implement procedures and administrative, technical, and physical controls to ensure donor privacy by restricting access to PII on hardcopy and electronic collection records (e.g., on Federal CCFs, in information entered into a computer system or database). Access to donor PII must be limited to those individuals requiring access to fulfill job duties. Such individuals must receive training to make them aware of their responsibilities for protecting the information. The confidentiality must be maintained from the time the donor PII is obtained through transmission/transport of the Federal CCF copies and record handling (i.e., storage, retrieval, and final destruction). Both hardcopy and electronic collection records must be stored and disposed of in a manner that ensures donor confidentiality is maintained.

The collector must not solicit or record a donor's medical information during the collection process.

## **Chapter 3. The Collection Site**

A collection site may be a permanent or temporary facility, located either at the work site or at a remote site, where donors present themselves for the purpose of providing a specimen for a drug test. When there is an immediate need to collect a specimen (e.g., a post-accident investigation) and there is no agency-designated site available, a public restroom may be used for the collection using the procedures for a monitored collection (see **Chapter 8, Section B**). The site must have all necessary personnel, supplies, equipment, facilities, and supervision to provide for specimen collection, security, and temporary storage until the specimen is transferred to an HHS-certified IITF or laboratory, and must have arrangements for the transfer of the specimens to a certified IITF or laboratory.

A facility used as a urine collection site must have:

1. Provisions to ensure donor privacy during the collection. Only authorized personnel and the donor may be present in the restricted access area where the collection takes place. The

collector must give the donor visual privacy while providing the specimen. The following facilities provide adequate privacy for urine collections:

- a. An enclosed stall in a multi-stall restroom
  - b. A single person restroom
  - c. A partitioned area that allows for individual privacy
  - d. A mobile restroom (e.g., a vehicle with an enclosed toilet stall).
2. A means for washing hands:
- a. If practical, the water source should be external to the restroom where collection occurs. If a water source is in the enclosure where the collection occurs, the collector must secure it prior to the collection or conduct a monitored collection (see **Chapter 8, Section B**).
  - b. If a water source is not available, another means (e.g., waterless cleanser, moist towelettes) outside the restroom is an acceptable alternative.
3. A suitable clean surface inaccessible to the donor for the collector to handle the specimen and complete the paperwork.
- a. If practical, the collector work area should be external to the restroom where collection occurs.
  - b. The collector work area may be inside the restroom only if the donor can have privacy while providing the urine specimen.
4. A secure temporary storage area for maintaining specimens until they are transferred to an HHS-certified IITF or laboratory. Specimens must be shipped within 24 hours or no later than the next business day. **Specimens that will not be shipped within 24 hours (e.g., collected on a Friday for shipment on Monday) should be kept in secure refrigerated storage.**
- Note: Specimens should NOT be exposed to high temperatures for an extended time.** These conditions may affect the test results of a urine specimen.
5. A restricted access area where only authorized personnel may be present during the collection.
6. Provisions for the collector to:
- a. Restrict access to collection supplies before, during, and after collection,
  - b. Store collection site records securely, and
  - c. Restrict donor access to items that could be used to adulterate, substitute, or dilute the specimen (e.g., soap, disinfectants, cleaning agents, water).

## Chapter 4. Federal Agency Blind Samples

The UrMG require each federal agency to have blind samples (i.e., negative samples, positive samples, adulterated samples, substituted samples) submitted to each HHS-certified laboratory that tests donor specimens for its workplace drug testing program. The blind samples may be purchased and supplied to the collector by the federal agency or the agency's external service provider, or purchased by the collector and submitted to an HHS-certified IITF or laboratory that the collector sends the agency's specimens. The UrMG specify the approximate percentage of each type (i.e., 75 percent negative, 15 percent positive for one or more drugs, 10 percent either adulterated or substituted). At a minimum, each federal agency must submit 3 percent blind samples with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly. The collector should distribute blind samples randomly with donor specimens rather than submitting blind samples as one group.

Each urine blind sample must meet the following requirements:

1. Drug-positive and -negative blind samples must be validated by the supplier as to their content using appropriate initial and confirmatory drug tests.
2. The supplier must provide the blind samples as matched A and B pairs, along with information on their content, validation, expected results, and stability to the collection site/collector that will send the blind samples to the laboratory or IITF. The supplier must also provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the HHS Secretary. If the collector purchases the samples for the federal agency's blind program, the collector must send the supplier's information (e.g., the content and concentration of the blind samples) to the MRO to enable the MRO to interpret the results and report them to the agency. The MRO will contact the supplier and/or collector as needed when investigating discrepant results.
3. Drug-positive blind samples must be fortified with one or more of the drugs or metabolites listed in the UrMG, and the concentration should be 1.5 to 2 times the initial drug test cutoff concentration.
4. Drug-negative blind samples (i.e., certified to contain no drugs) must be validated by the supplier as negative using the appropriate initial and confirmatory tests.
5. Substituted or adulterated blind samples must be validated by the supplier using appropriate initial and confirmatory specimen validity tests, and must be shown to meet substitution or adulteration criteria specified in the UrMG at the time of validation.

Each blind sample must be submitted as a split specimen (specimens A and B) with a current Federal CCF (paper or electronic) that the HHS-certified laboratory or IITF uses for donor specimens.

1. The collector provides the required information to ensure that the Federal CCF has been properly completed, including fictitious donor identification in Step 1c of the Federal CCF and fictitious donor initials on the A and B specimen bottle labels/seals.

2. The collector indicates that the sample is a "blind sample" on the MRO copy where the donor would normally provide a signature (Step 5 on Copy 2 of the Federal CCF).
3. The collector may either discard Copies 4 and 5 of a paper Federal CCF (the employer copy and the donor copy) or maintain them with Copy 3 of the Federal CCF (the collector copy).

## **Chapter 5. The Federal Drug Testing Custody and Control Form (Federal CCF)**

Federal agencies are required to use the Office of Management and Budget (OMB)-approved Federal CCF when collecting specimens for their workplace drug testing programs. Federal CCFs are available from a number of different sources (e.g., laboratories, collectors, third party administrators, MROs, ECCF providers). The same Federal CCF is used for urine and oral fluid specimens. **Note:** References to instrumented initial test facilities (IITFs) in this chapter apply to urine specimens only.

**2020 Federal CCF:** OMB approved the use of the 2020 Federal CCF as of September 1, 2020, for urine and oral fluid specimens. The 2020 Federal CCF may be used as a paper or electronic form. Acceptable formats are described in **Section A** below.

A proof of the current Federal CCF, guidance for its use, and Instructions for Completing the Federal CCF (i.e., separate instructions for urine specimens and for oral fluid specimens) are on the SAMHSA website: <https://www.samhsa.gov/workplace>.

**2017 Federal CCF:** OMB originally extended the use of the expired 2017 Federal CCF **for urine specimens** until August 30, 2021 and subsequently extended its use until August 31, 2023. The 2017 Federal CCF is not authorized for use with oral fluid specimens; the 2020 Federal CCF should be used for oral fluid specimens. Beginning August 31, 2023, the 2020 Federal CCF must be used for federally regulated specimens, and the test facility (laboratory or IITF) must treat the use of the 2017 Federal CCF for urine specimens as a correctable discrepancy. See **Section B.1** below regarding use of an incorrect CCF.

Employers are prohibited from using the Federal CCF for:

1. Private-sector employee drug testing, with the exception of transportation industry testing conducted under the Department of Transportation (DOT) regulations.
2. State workplace drug testing programs
3. Department of Justice drug testing programs

### **A. Acceptable Formats for a Federal CCF**

A federal agency may use the Federal CCF as:

1. A paper form: a five-part form that is either preprinted or printed at the collection site before the collection, or

2. An electronic form (ECCF): either a digital (paperless) form or a combination electronic and paper form. All ECCFs must be the functional equivalent of a paper Federal CCF with respect to integrity, accuracy, and accessibility.

The two types of combination electronic and paper ECCF systems are:

- a. **Type 1**: The collector uses an ECCF system to document the collection process, then prints Copy 1 and Copies 2–5 (without signatures). The donor signs in Step 5 of Copies 2–5 using a wet-ink signature and the collector signs in Step 4 of Copies 1–5 using a wet-ink signature. The electronic form is not signed.
- b. **Type 2**: The collector uses an ECCF system to document the collection process, the collector and donor sign using electronic signatures (the donor uses a digitized signature), and the collector prints Copy 1 with his or her electronic signature. The printout of ECCF Copy 1 must be designated as the single authoritative copy of the ECCF.

**HHS-certified test facilities must receive approval from HHS before accepting regulated specimens collected using an ECCF system.** SAMHSA maintains the list of HHS-certified test facilities (laboratories and IITFs) approved to use an ECCF, with the ECCF system(s) that each is authorized to use, on the SAMHSA website: <https://www.samhsa.gov/workplace>.

If a laboratory or IITF receives a specimen that was collected using an ECCF system whose use has not been approved by SAMHSA for that test facility, **they will reject the specimen.**

All collection sites must maintain a supply of paper Federal CCFs. A paper Federal CCF must be used in the event of a software/hardware problem preventing collections using an ECCF. In addition, collection sites must have the ability to print the Federal ECCF on demand. This capability allows the collector to print the Federal CCF in the event of a problem preventing completion of a collection using an ECCF (e.g., allowing for handwritten collector and donor signatures in the event of a problem with the electronic signature system or when a donor refuses to sign electronically but agrees to sign using a wet-ink signature).

Federally regulated employers and drug testing service providers (e.g., collectors, test facilities, MROs) who use an ECCF must implement procedures and administrative, technical, and physical controls to ensure the authenticity, integrity, and confidentiality of electronic records, and to ensure that electronic signatures are the legally binding equivalent of traditional handwritten signatures. These procedures and controls include, but are not limited to:

1. System validation.
2. The ability to generate accurate and complete copies of records in both human-readable and electronic form suitable for inspection, review, and copying upon request of authorized parties (e.g., the MRO, federal agency, or SAMHSA).
3. Protection of records to enable accurate and ready retrieval throughout the records retention period.
4. Limiting system access to authorized individuals (e.g., trained collectors). Procedures must be in place for managing the user authentication system (e.g., assignment, review, revocation).

5. Secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete records from the time of initiation of the Federal CCF (changes should be evident when reviewing the original record, and any electronic or paper copy of the original record).
6. Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

## **B. Federal CCF Problems**

See also **Appendix A: Federal CCF Decision Trees for Collectors.**

### 1. Use of an Incorrect CCF

- a. As noted above, if a laboratory or IITF receives a specimen that was collected using an ECCF system whose use has not been approved by SAMHSA for that test facility, they must reject the specimen.
- b. In rare cases, a collector may use a non-federal CCF or an expired Federal CCF for a federal agency collection by mistake or as the only means to conduct a collection under unusual circumstances (e.g., post-accident test with insufficient time to obtain an OMB-approved Federal CCF).
  - If the collector realizes an incorrect CCF was used, they must include remarks on the CCF noting that it is a federal agency specimen or that an expired Federal CCF was used, provide the reason that the incorrect form was used, and include all collection information required on the current Federal CCF for that specimen type (urine or oral fluid). (Instructions for using the current Federal CCF are in **Section D** below.)
    - If the CCF used for the collection does not include space for all collection information required on the current Federal CCF, the collector must include the missing information in a signed memorandum for the record (MFR) sent to the test facility with the specimen.
    - If a laboratory or IITF discovers or is notified that a federal agency specimen was collected using an incorrect CCF and the collector did not provide explanatory collector remarks and required 2020 Federal CCF information on the CCF or on a signed MFR sent with the specimen, the test facility will contact the collector for an MFR to recover the missing information, with the following exception.
      - **For an oral fluid collection device with diluent**, if a laboratory receives an oral fluid specimen with an incorrect CCF and no collector documentation that they observed the device volume indicator(s) during the collection (i.e., on the CCF or a signed MFR sent with the specimen), the laboratory will reject the specimen. **An MFR cannot be used to recover this missing information after the collection.**
    - If an MRO discovers the use of a non-federal or expired Federal CCF, the collector is notified to provide an MFR to the MRO with the reason for using the

incorrect form and with other information required on the 2020 Federal CCF, with the following exception.

- **For an oral fluid collection device with diluent**, if a laboratory receives an oral fluid specimen with an incorrect CCF and no collector documentation that they observed the device volume indicator(s) during the collection (i.e., on the CCF or a signed MFR sent with the specimen), the laboratory will reject the specimen. **An MFR cannot be used to recover this missing information after the collection.**
- c. The collector must take **immediate** steps to provide an MFR when notified. A laboratory or IITF holds specimens for a short time (i.e., a minimum of five business days) after notifying the collector, before reporting a “rejected for testing” result to the MRO, who will cancel the test.
- In the case of an expired (urine-only) CCF for a urine specimen, if the collector is not available, the collection site supervisor may sign the MFR.

## 2. Incorrect CCF Copy

Section E below describes proper distribution of Federal CCF Copies 1–5. The collector sends the **Test Facility Copy (Copy 1)** with the specimen to the laboratory or IITF.

- a. If the collector sends an incorrect CCF copy (i.e., Copy 2–5) with the specimen, the laboratory or IITF will not test the specimen until the collector provides documents to recover the error. The collector must send a signed explanatory MFR and the original Federal CCF Copy 1 signed by the collector using a wet-ink signature. The collector must send the Federal CCF Copy 1 with their wet-ink signature by courier or mail to the test facility (i.e., it is not acceptable to send a fax or pdf copy).
- b. The collector must take **immediate** steps to provide an MFR when notified. In the case of an ECCF reprint error, if the collector no longer works at the collection site, the collection site supervisor may sign the MFR. A laboratory or IITF holds specimens for a short time (i.e., a minimum of five business days) after notifying the collector, before reporting a rejected for testing result to the MRO, who will cancel the test.

## 3. Reprint ECCF Copy 1

For a Combination Electronic and Paper Federal CCF that has been signed by the collector and donor using electronic signatures, the collector must send the printout of Copy 1 designated as the single authoritative copy of the ECCF with the specimen.

- a. The ECCF system will distinguish the authoritative copy from subsequent printed copies of Copy 1 (e.g., identifying subsequent copies as “Reprint”). If there is a problem with printing the authoritative copy (e.g., a printer error):
  - The collector must sign the reprinted Copy 1 (in the presence of the donor) using a wet-ink signature in Step 4 (near their printed name and electronic signature) to designate this copy as the single authoritative copy.

- The collector (or the ECCF system) must include a remark in Step 2 of the ECCF reprint noting the reason for reprinting Copy 1. Alternatively, the collector must send a signed MFR to the laboratory or IITF with the specimen, including the reason that a reprinted Copy 1 was sent with the specimen.
  - If the collector fails to sign the ECCF reprint using a wet-ink signature and/or fails to provide an explanatory remark or an MFR, the laboratory or IITF will not test the specimen, but will hold the specimen pending receipt of collector documents to recover the error(s). The collector must reprint the ECCF Copy 1 for the specimen, sign using a wet-ink signature, and provide an explanatory MFR. The collector must send the reprint ECCF with their wet-ink signature by courier or mail to the test facility (i.e., it is not acceptable to send a fax or pdf copy).
- b. The collector must take **immediate** steps to provide an MFR when notified. In the case of an ECCF reprint error, if the collector no longer works at the collection site, the collection site supervisor may sign the MFR. A laboratory or IITF holds specimens for a short time (i.e., a minimum of five business days) after notifying the collector, before reporting a rejected for testing result to the MRO, who will cancel the test.

## C. Federal CCF Content Requirements

### 1. Test Facility Identification

At the top of the Federal CCF, the test facility (i.e., HHS-certified laboratory or IITF) must be identified by one of the following:

- a. The name and address of the specific test facility,
- b. A list of addresses with checkboxes to allow the collector to check the box for the specific laboratory or IITF to which the specimen will be shipped, or
- c. A corporation name and telephone number. **Note:** Either the collector will annotate the address of the specific test facility within the corporation to which the specimen will be shipped, or the test facility that receives the specimen for testing will annotate its address.

### 2. Labels/Seals

The tamper-evident labels/seals for the specimen bottles/tubes may be at the bottom of Copy 1 or may be separate from the form:

- a. There must be two labels/seals: one marked with the letter “A” to designate the primary specimen and the other marked with the letter “B” to designate the split specimen.
- b. Each label/seal must have:
  - The same specimen ID number that is at the top of the Federal CCF,
  - A place for the collector to annotate the date of the collection, and

- A place for the donor to initial the label/seal after it is placed on the specimen bottle/tube.
- **For oral fluid specimens:** The label/seal must not cover the expiration date on the oral fluid specimen tube and must allow visual assessment of the contents of the tube.

### 3. Required Statements and Instructions

Wording of required statements must be identical to that on the OMB-approved Federal CCF. Instructions and statements must be provided as follows:

#### a. **Instructions for Completing the Federal Drug Testing Custody and Control Form for Urine and Oral Fluid Specimen Collections**

- Separate Instructions for Completing the Federal CCF (for urine specimens and for oral fluid specimens) are available for downloading on the SAMHSA website: <https://www.samhsa.gov/workplace/resources>.
- The collector must provide the instructions to the donor (e.g., hardcopy, onscreen, posted at the collection site).

#### b. **Public Burden Statement**

- Paper Federal CCF: The Public Burden Statement is printed on each Federal CCF copy (i.e., on the back of Copies 1 through 5).
- Electronic CCF or Combination Electronic and Paper Federal CCF: The Public Burden Statement is provided to employers and donors on the printed or electronically transmitted ECCF (Copies 4 and 5) and to collectors on the ECCF (Copy 3) maintained in collector/collection site records. The statement must be provided to test facilities and MROs on a separate page (hardcopy or electronic).

#### c. **Privacy Act Statement (For Federal Employees Only)**

- Paper Federal CCF: The Privacy Act Statement is printed on the back of the donor copy (Copy 5).
- Electronic CCF or Combination Electronic and Paper Federal CCF: The Privacy Act Statement is provided to donors on the printed or electronically transmitted Federal CCF (Copy 5).

### **D. Federal CCF Instructions for Use with Urine Collections**

**Note: Chapter 7, Section C** includes step-by-step instructions for urine collections, including instructions for collector and donor entries on the Federal CCF.

**Step 1.** To be completed by the collector or federal agency representative prior to the donor providing a specimen.

1. The employer's name, address, telephone and fax numbers, and employer ID number (if applicable).
2. The specific MRO name, address, telephone number, and fax number.
3. Donor identification (e.g., SSN, employee ID number, or commercial driver's license number and state). The collector enters the donor identification after verifying the donor's identity. If the donor refuses to provide their SSN or ID number, the collector enters a remark in Step 2 on Copy 1.
4. The testing authority box indicating under which federal agency the specimen is being collected. The HHS box is checked for a federal agency employee or pre-employment specimen.
5. The appropriate box indicating the reason for the drug test. If the test is to be performed for a reason other than those listed on the Federal CCF, the "Other" box is checked and the specific reason is recorded.
6. The appropriate box for the drug tests to be performed. If the test is to be performed for a drug other than those listed on the Federal CCF, the "Other" box is checked and each specific drug is recorded.
7. The collection site address.
8. Collector contact information including telephone number, fax number, and other (e.g., email address).

**Step 2.** To be completed by the collector after receiving the specimen from the donor and measuring the temperature of the specimen within 4 minutes. This step requires the collector to mark the appropriate boxes to indicate:

1. Specimen type. Check the **URINE** checkbox at the top of Step 2.
2. Collection type: Check the appropriate box to indicate whether the collection was a split specimen or single specimen collection. **Note:** Split specimens are required for all federal agency collections. If no specimen was provided, check the None Provided box and enter a remark and print your name in Step 2. You may, but are not required to, sign the Step 2 Remarks.
3. **URINE** entries:
  - a. **Temperature.** Check the appropriate box to indicate whether the temperature of the specimen was or was not within the required temperature range. If temperature was outside the acceptable range, the collector enters a remark in Step 2 and takes action as required.
  - b. **Observed.** If a direct observed collection was performed, check the Observed box and enter the following information on the Remarks line in Step 2.
    - Ask the donor to write the donor's gender and initial it.

- Write the name and gender of the observer and the reason for an observed collection.  
**Note:** If there is insufficient room on the Remarks line, the collector may provide a separate MFR explaining the use of an observed collection. The collector must send the MFR to the test facility.

4. **Remarks:** Enter collector remarks and take action as needed (e.g., unusual behavior or appearance of the donor; failed collection attempts; unusual color, presence of foreign objects or material in the specimen).

**Step 3.** This section lists actions to be performed by the collector and donor at the end of the collection, after the primary (A) and split (B) specimens have been collected. The collector assists the donor with completing the donor section of the Federal CCF in **Step 5 on Copy 2.**

1. Record or instruct the donor to record the donor's information:
  - a. Printed name
  - b. Date of collection
  - c. Email address, daytime, and evening telephone numbers
  - d. Date of birth
2. Instruct the donor to:
  - a. Review information transcribed by the collector on the CCF
  - b. Read the donor certification statement and information in Step 5 on possible MRO requests for donor medication information (i.e., based on MRO review of test results)
  - c. Sign and date the certification statement
3. If the donor refuses to provide their information or to sign the certification statement, enter a remark in Step 2 on Copy 1.

For ECCFs: if the donor refuses to sign electronically but is willing to sign a paper CCF with a wet-ink signature, print the ECCF, Copies 1–5. The donor must sign in Step 5 of Copies 2–5 using a wet-ink signature and the collector must sign in Step 4 of Copies 1–5 using a wet-ink signature.

**Step 4.** To be initiated by the collector and completed at the test facility.

1. Sign the collector certification statement in Step 4 on Copy 1 to certify that the specimen was collected, labeled, sealed, and released for shipment to the HHS-certified IITF or laboratory in accordance with federal requirements.
2. Include your printed name.
3. Record the following:

- a. Date of collection
- b. Time of collection
- c. The specific name of the delivery service to which the specimen bottles are released for shipment to the HHS-certified IITF or laboratory

**Note:** Copy 1 entries in Step 4 below the first bold line and in the subsequent steps are made at the HHS-certified IITF or laboratory.

## **E. Federal CCF Distribution**

**Note:** Employers, collectors, test facilities, and MROs who send or receive CCFs electronically are responsible for ensuring the security of data transmissions and limiting access to any data transmission, storage, and retrieval systems.

### **Paper CCFs and Combination Electronic and Paper CCFs**

#### 1. Copy 1 (Test Facility Copy)

The collector sends the signed Copy 1 with the specimen to the HHS-certified laboratory or IITF. Copy 1 is placed in the package with the specimen (i.e., in a compartment separate from the specimen bottles).

For Combination Electronic and Paper CCFs: Copy 1 sent with the specimen must be either the single authoritative copy, or a reprint of Copy 1 that has been signed by the collector using a wet-ink signature.

#### 2. Copy 2 (MRO Copy)

The collector sends Copy 2 signed by the donor to the MRO via courier, mail, fax, or other electronic transmission method.

For a Paper Federal CCF: If a copy of Copy 2 is sent to the MRO via fax or provided electronically, the collector maintains the original Copy 2 in the collection site records.

#### 3. Copy 3 (Collector Copy)

Copy 3 is maintained in the collection site records.

#### 4. Copy 4 (Employer Copy)

The collector sends Copy 4 to the federal agency employer via courier, mail, fax, or other electronic transmission method.

#### 5. Copy 5 (Donor Copy)

The collector gives Copy 5 to the donor as a hardcopy after the collection is complete or sends it electronically.

## **Digital Federal CCFs**

### 1. Copy 1 (Test Facility Copy)

- a. Copy 1 signed by the collector is electronically provided to the HHS-certified laboratory.
- b. In addition, the collector must either:
  - Include a printed copy of the Test Facility Copy (Copy 1) in the package with the specimen (i.e., in a compartment separate from the specimen bottles), or
  - Apply a label to the outside of the specimen package, with the specimen ID number, test facility name and contact information, and collection site name and contact information.

### 2. Copies 2 through 5

- a. Copy 2 signed by the donor is electronically provided to the MRO.
- b. Copy 3 is maintained in the collection site records.
- c. Copy 4 is provided electronically to the employer.
- d. Copy 5 is provided to the donor as a hardcopy or electronically.

## **Chapter 6. Verification of Donor Identity**

The donor must provide appropriate identification to the collector upon arrival at the collection site.

**Acceptable** forms of identification are:

1. A photo ID (e.g., driver's license, employee badge issued by the employer, or an alternative photo ID issued by a federal, state, or local government agency), or
2. Positive identification by the supervisor of the donor or by a federal agency representative.

If the identity of the donor cannot be established, the collector must not proceed with the collection.

**Unacceptable** forms of identification are:

1. Identification by a co-worker,
2. Identification by another donor,
3. Non-photo ID (e.g., social security card, credit card, union or other membership cards, pay vouchers, voter registration card), or
4. A faxed copy or photocopy of an identification document.

## Chapter 7. Urine Specimen Collection

### A. Collection Site Security

The collection site must have a restricted access area to prevent unauthorized access to specimens, collection supplies, and collection site records. A permanent site that is used solely for specimen collections must be secured at all times. At facilities that are not dedicated specimen collection sites, the area of the site used for specimen collections must be secured as a restricted access area during the time a specimen is collected.

A collector must:

1. Prohibit unauthorized personnel from entering the collection site during the collection.
2. Ensure the privacy of the donor.
3. Perform only one donor collection at a time.
4. Restrict access to collection supplies before, during, and after the collection.
5. Ensure that only the collector and the donor are allowed to handle the unsealed specimen.
6. Ensure that chain of custody is maintained and documented from the time of collection until the labeled and sealed specimen bottles are sealed in the specimen package for transport to the laboratory.
7. Ensure that the Federal CCF is completed and CCF Copies 1–5 are distributed as required.
8. Ensure that specimens are transported to the test facility in a sealed and secure transport container to minimize the possibility of damage during shipment and to prevent undetected tampering.

### B. Collection Supplies

The following items must be available at the collection site to conduct proper urine collections:

1. **Single-use plastic collection containers:** Each collection container must not substantially affect the composition of drugs and/or metabolites in the urine specimen collected and must be:
  - a. Supplied as an individually sealed item using a tamper-evident system (e.g., in a sealed plastic bag, shrink wrapped, with a peelable or sealed lid, or another easily visible tamper-evident system),
  - b. Large enough to easily catch and hold at least 55 mL of urine, and
  - c. Graduated with volume markings clearly showing the volume (e.g., 45 mL).

2. **Single-use plastic specimen bottles:** Each specimen bottle with cap must not substantially affect the composition of drugs and/or metabolites in the urine specimen collected and must be:
  - a. Supplied as individually sealed bottles with a tamper-evident system (e.g., using plastic bag, shrink wrap, with a peelable or sealed lid, or another easily visible tamper-evident system),
  - b. Able to hold at least 35 mL,
    - The split specimen bottle may be the same size as or smaller than the primary specimen bottle, but must be able to hold at least 20 mL.
  - c. Leak-resistant (i.e., have a screw-on or snap-on cap that prevents leakage),
  - d. Marked clearly to indicate the minimum levels of urine to be poured into each bottle (30 mL for the primary specimen and 15 mL for the split specimen),
  - e. Designed so that the required tamper-evident bottle label/seal from the Federal CCF is not damaged when the donor initials it and has no overlap that conceals printed information, and
  - f. Sufficiently transparent to enable an objective assessment of the urine specimen appearance and identification of abnormal physical characteristics without opening the bottle.
3. **Thermometer:** The thermometer must be capable of temperature readings between 90°-100°F (32°-38°C). The thermometer must accurately measure the temperature of the specimen and not contaminate the specimen. The thermometer may be affixed to or built into the collection container as supplied or placed on the collection container after the donor gives the collection container with the specimen to the collector. Alternately, the collector may use another technology to measure the specimen temperature (e.g., thermal radiation scanning), providing the thermometer does not come into contact with the specimen.
4. **Federal CCFs:** An OMB-approved Federal CCF as described in **Chapter 5** must be used for the collection. All collection sites, including those using ECCFs (digital and/or combination electronic and paper Federal CCFs), should maintain a supply of paper Federal CCFs.
5. **Tamper-evident labels/seals:** Tamper-evident labels/seals are used to identify and seal the specimen bottles containing the primary (A) and split (B) specimens. Occasionally, a tamper-evident label/seal will not properly adhere to the specimen bottle (e.g., due to moisture, temperature, or specimen bottle material). If this occurs, follow instructions in **Chapter 8, Section G** for using another tamper-evident seal.
6. **Leak-resistant container:** A container (e.g., plastic bag) that is leak-resistant and large enough to hold two specimen bottles.
7. **Specimen package:** The sealed, tamper-resistant container (e.g., plastic bag, box) that contains the specimen bottle(s) and Federal CCF from a urine drug test collection. **Note:** When an electronic Federal CCF was used for the collection, the collector must either

(1) include a printed copy of the Federal CCF (for informational purposes only) in the specimen package or (2) apply a label to the outside of the specimen package with the specimen identification number, test facility name and contact information, and collection site name and contact information.

8. **Absorbent material:** The absorbent material is placed inside the leak-resistant container with the specimen bottles in case a specimen bottle leaks during shipment. The U.S. Postal Service and other express carriers require the use of absorbent material when shipping biological materials.
9. **Shipping container:** The container (e.g., box, mailer, bag) in which the collector places one or more specimen packages for transport to an IITF or laboratory. The shipping container must be securely sealed to prevent loss of a specimen during transport. It is not necessary to use a shipping container if a courier hand-delivers the specimen package directly from the collection site to the IITF or laboratory.
10. **Bluing agent:** Bluing agent is added to the toilet bowl and water tank to prevent undetected specimen dilution by the donor.
11. **Disposable gloves:** HHS recommends that collectors use single-use disposable gloves while handling specimens. The Occupational Safety and Health Administration has specific standards addressing protection of employees who are exposed to potentially infectious body fluids (29 CFR Part 1910.1030).

### **C. Collection Procedure**

1. Prepare the collection site to collect urine specimens.
2. Assemble supplies.
  - a. Ensure that there is bluing agent in the toilet. If no bluing agent is available or if there is an automatic flushing system, turn off the water supply and flush the toilet to remove any water in the toilet when possible.
  - b. Turn off the water supply or secure water sources inside the restroom.
3. Provide a means for the donor to wash their hands under your direct observation. If there is not a restroom or a sink within the collection area, provide another means (e.g., waterless cleanser, moist towelette).
  - a. If a water source inside the restroom cannot be turned off or secured, you must perform a monitored collection as described in **Chapter 8, Section B**.
  - b. Remove any soap, cleanser, disinfectant, or other potential adulterants, and
  - c. Inspect and/or secure areas or items that could be used to conceal adulterants (e.g., false ceilings, ledges, trash cans, towel dispensers).
4. Begin the collection process without delay when the donor arrives at the collection site. For example, the collection should not be delayed because an authorized employer or employer

representative is late in arriving. **If the donor states that they are unable to provide a urine specimen, continue with the collection procedure through Step 13 below.**

- a. If a donor fails to arrive at the collection site at the assigned time for the drug test, follow the federal agency policy or contact the federal agency representative to obtain guidance on the appropriate action to be taken.
5. Verify the donor's identity with a photo identification (see **Chapter 6**). If the donor requests, you must provide identification (e.g., employee badge, employee list).

See **Chapter 5, Section D** for step-by-step instructions for completing the Federal CCF.

Instructions below apply to all Federal CCF formats (see ECCF definitions and requirements in **Chapter 5, Section A**).

6. Obtain the paper Federal CCF or log onto the Federal ECCF system for the collection.
7. Ensure that the specimen identification number on the Federal CCF matches the identification number printed on each specimen bottle label/seal and on the specimen package label (if any).

**Note:** Some ECCF systems require the collector to scan the barcoded specimen ID number on each bottle label/seal and add that specimen ID number to the ECCF. This step may be later in the collection process (as directed by the ECCF system).

8. Verify the preprinted laboratory information (e.g., name and address) at the top of the Federal CCF, including the laboratory account number (if applicable).
9. Record and verify the information in Step 1 of the Federal CCF. Edit entries as needed. For a paper CCF, line through incorrect information, handwrite the correct information and initial and date the change.
10. Describe the basic collection procedure to the donor and inform the donor that the Instructions for Completing the Federal Custody and Control Form for a Urine Collection are available upon request. Answer any reasonable and appropriate questions that the donor has about the collection process.
11. To deter adulteration or substitution of the specimen:
  - a. Ask the donor to remove any unnecessary outer clothing (e.g., coat, jacket, hat) that could be used to conceal items or substances that could be used to adulterate or substitute the urine specimen.
    - It is not necessary for the donor to remove a hat or head covering that the donor refuses to remove based on religious practice.
    - It is not necessary for the donor to remove their footwear, unless you suspect that they are concealing something that may be used to adulterate or substitute the specimen.

- b. Take steps to safeguard the donor's outer clothing and other personal belongings (e.g., briefcase, purse). The donor may retain their wallet.
  - The belongings may be left unsecured if they remain within the line of sight of the collector and the donor, and out of the donor's reach, until the end of the collection, or
  - The belongings may be secured (e.g., in a lockable cabinet with access controlled by the donor, in a sealed bag with a tamper-evident seal).
- c. Ask the donor to empty their pockets and display the items.
  - If there are no items that can be used to adulterate a specimen, instruct the donor to return the items to their pockets and continue the collection procedure (i.e., with Step 12).
  - If an item is present whose purpose is to adulterate, substitute or dilute the specimen (e.g., a commercial drug culture product or other substance for which the donor has no reasonable explanation), this is considered a refusal to test. You must stop the collection and report the refusal to test to the federal agency to ensure immediate notification is received (see **Chapter 8, Section F**). Create an MFR to document the item (e.g., written description, photograph), and sign and date the MFR.
  - If an item that could be used to adulterate, substitute, or dilute a specimen (e.g., common personal care products such as eyedrops, mouthwash, or hand sanitizer) appears to have been inadvertently brought to the collection site, document the item in an MFR (e.g., written description, photograph), sign and date the MFR, safeguard the item with the donor's belongings, and continue the collection procedure (i.e., with Step 12).
  - If the donor refuses to display the items in their pockets, this is considered a refusal to test. Stop the collection and report the refusal to test to the federal agency to ensure immediate notification is received (see **Chapter 8, Section F**).

**Note:** The collector must work with only one donor at a time and must protect each donor's privacy. Only authorized personnel and the donor may be present in the restricted access area where the collection takes place. In addition, the collector must maintain the security and confidentiality of donor information on the Federal CCF for each donor.

#### 12. Prepare for the collection:

- a. Instruct the donor to wash and dry their hands under your observation.
  - Liquid soap is preferred over bar soap because bar soap gives the donor the opportunity to conceal soap shavings under their fingernails in an attempt to adulterate the specimen.
- b. After washing their hands, the donor must remain in your presence and not be allowed access to any water fountain, faucet, soap dispenser, cleaning agent, or other materials

which could be used to adulterate, substitute, or dilute a specimen. Instruct the donor to keep their hands within view and avoid touching items or surfaces.

- If the donor refuses to wash their hands when instructed, this is considered a refusal to test. You must stop the collection and report the refusal to test to the federal agency.
- c. Provide or allow the donor to select the collection kit or packaged collection container (if it is separate from the kit) from the available supply.
  - d. Unwrap or break the seal of the kit or collection container in view of the donor. You may allow the donor to perform this step.
    - Both the collector and the donor must be present.
    - Only the seal on the collection container is broken at this time (i.e., the specimen bottles remain sealed/wrapped).

**Note:** If the donor has stated that they are unable to provide a specimen, at this point in the collection, request that the donor enter the restroom and attempt to provide a specimen. If the donor comes out of the stall with an empty collection container, they have demonstrated the inability to provide a specimen. Follow the Insufficient Specimen procedure in **Chapter 8, Section C**, and **Appendix D**.

13. Direct the donor to:

- a. Provide the specimen in the privacy of the restroom/stall/partitioned area to be used for the collection,
- b. Provide a specimen of at least 45 mL,
- c. Not flush the toilet, and
- d. Return with the specimen as soon as they have finished completing the void.
  - You may inform the donor that the temperature of the urine specimen must be read within 4 minutes after the void to be valid. Longer wait periods may cause the temperature to be out of range and necessitate an observed collection.
  - A reasonable time limit may be set for completing the void.

**Note:** Neither the collector nor anyone else may go into the restroom with the donor, except in the case of a direct observed collection (see **Chapter 8, Section A**) or a monitored collection (see **Chapter 8, Section B**).

**Note:** You must note any unusual behavior or appearance of the donor on the Federal CCF. If you detect any conduct that clearly indicates an attempt to tamper with a specimen, you must report a refusal to test immediately to the federal agency.

**Note:** Both you and the donor must maintain visual contact with the specimen from the time the specimen is transferred to you until specimen bottles have been sealed for shipment to the IITF or laboratory.

**Note:** After receiving the specimen from the donor, whenever practical, you may allow the donor to wash their hands and to flush the toilet. (The collector may inspect the toilet for any materials indicative of specimen tampering prior to flushing.)

14. After you receive the specimen from the donor, read the temperature.

- a. Do this within 4 minutes after the void.
- b. Mark the appropriate box in Step 2 of the Federal CCF:
  - If the temperature is **within the acceptable range** (32° - 38°C; 90°-100°F), mark “Yes” and proceed with the collection procedure. Go to Step 15.
  - If the temperature is **outside the acceptable range**, mark “No.” You will perform a second, direct observed collection, and send both specimens to an HHS-certified laboratory (not an IITF) for testing. (See exception in first Note below.)
    - Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF for the first specimen to identify this as the first of two specimens collected and the reason why two specimens were collected.
    - Complete the first collection before initiating the second collection, including Step 15 (examining the physical characteristics of the urine).
    - Begin the collection of a second specimen using a direct observed collection procedure (see **Chapter 8, Section A**) and a new collection kit (i.e., a new collection container and a new Federal CCF).
    - Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF for the second specimen to indicate why two specimens were collected, including a cross reference to the specimen identification number of the first specimen.

**Note:** The specimen with unacceptable temperature and its Federal CCF are sent to an HHS-certified laboratory regardless of the specimen volume. **Exception:** If the unacceptable temperature is due to a measurement problem (e.g., no reading due to extremely low volume, temperature strip failure) discard the urine collected and immediately begin a second collection using the same Federal CCF and the same procedures (not directly observed). Use a new collection container for the second collection.

**Note:** If the donor provides less than 45 mL for the second specimen, follow the Insufficient Specimen procedures in **Chapter 8, Section C**. Discard the second specimen. Do not send the second specimen for testing if the volume is less than 45 mL.

**Note:** If the donor refuses to provide a second specimen or leaves the collection site before the collection process is completed, this is considered a refusal to test (see **Chapter 8, Section F**).

Discard any urine, document the refusal to test on the Federal CCF and send all copies of the Federal CCF to the federal agency's designated representative.

15. Inspect the specimen for adulteration or substitution by examining the physical characteristics of the urine.

a. Note any abnormal characteristics such as:

- Unusual color (e.g., specimen is blue),
- Presence of foreign objects or material,
- Unusual odor (e.g., bleach), or
- Signs of adulteration (e.g., excessive foaming when shaken).

b. If there are no abnormal characteristics indicative of adulteration or substitution by the donor, proceed with the collection procedure. Go to Step 16.

c. If you observe any abnormal characteristic(s) that appears to be due to adulteration or substitution by the donor, you will perform a second, direct observed collection and send both specimens to an HHS-certified laboratory (not an IITF) for testing:

- Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF for the first specimen to identify this as the first of two specimens collected and the reason why two specimens were collected.
- Complete the first collection before initiating the second collection by continuing with the procedure in Step 17.
- Begin the second specimen collection using a direct observed collection procedure (see **Chapter 8, Section A**) and a new collection kit (i.e., a new collection container and a new Federal CCF).
- Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF for the second specimen to indicate why two specimens were collected, including a cross reference to the specimen identification number of the first specimen.

d. Follow the additional instructions below (also see **Appendix C, Two Specimens from the Same Collection Event**).

- The specimen with abnormal physical characteristics and its Federal CCF are sent to an HHS-certified laboratory regardless of the specimen volume.
- If the donor provides less than 45 mL for the second specimen, follow the Insufficient Specimen procedures in **Chapter 8, Section C**. Discard the second specimen. Do not send the second specimen for testing if the volume is less than 45 mL.
- If the donor refuses to provide a second specimen or leaves the collection site before the collection process is completed, this is considered a refusal to test (see

**Chapter 8, Section F).** Discard any urine, document the refusal to test on the Federal CCF and send all copies of the Federal CCF to the federal agency's designated representative.

16. Check the specimen volume to ensure that the specimen contains at least 45 mL of urine.
  - a. If the specimen volume is at least 45 mL, complete the specimen collection procedure continuing with Step 17.
  - b. If the specimen volume is less than 45 mL, discard the specimen and immediately begin a second collection using the same procedures and the same Federal CCF. Use a new collection container for the second collection.

**Note:** If the donor refuses to attempt to provide a second specimen or leaves the collection site before the collection process is completed, this is considered a refusal to test (see **Chapter 8, Section F**).

- c. When a second specimen must be collected, follow the Insufficient Specimen procedure in **Chapter 8, Section C**.
  - When the donor hands you the second specimen, continue with the collection procedure, including Step 14 (checking specimen temperature) and Step 15 (examining physical characteristics of the urine).
  - If the donor is unable to provide at least 45 mL for the second specimen after a period of three hours, stop the collection procedure. Record the reason for not collecting a urine specimen on the Federal CCF, and notify the federal agency's designated representative for authorization of an alternate specimen to be collected. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. You must send the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative (see **Chapter 8, Section C**).
  - If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen in accordance with the UrMG. If the donor refuses to provide an alternate specimen, the collector stops the collection and reports the refusal to test (see **Chapter 8, Section F**).
17. Unwrap the sealed specimen bottles in the donor's presence.
18. In the donor's presence, pour the urine from the specimen collection container into the two specimen bottles labeled "A" and "B".
  - a. Pour at least 30 mL into the "A" Bottle and at least 15 mL into the "B" bottle.
  - b. Secure the lid/cap on each bottle.

19. Seal the A and B specimen bottles while the donor watches, positioning the appropriate label/seal over the lid/cap of each bottle to ensure that the lid/cap cannot be removed without breaking the label/seal.
20. Discard any excess urine remaining in the collection container after the bottles have been filled with the appropriate volumes of urine.
  - a. The only exception is when the excess urine is being used to conduct clinical tests in conjunction with a physical examination that is required by the federal agency. No further tests may be conducted on the excess urine.
21. Write the date on the tamper-evident labels/seals.
22. Ask the donor to initial the label/seal on each bottle, using care to avoid damage.
  - If the donor fails or refuses to initial the seals, note this on the Remarks line in Step 2 of the Federal CCF and complete the collection process. This is not considered a refusal to test.
23. Inform the donor that it is not necessary for them to continue observing the collection procedure after the bottles have been sealed, and that they are allowed to wash their hands.
24. Complete the Federal CCF.

**See Chapter 5, Section D for step-by-step instructions for completing the Federal CCF.**

**Instructions below apply to all Federal CCF formats (see ECCF definitions and requirements in Chapter 5, Section A).**

- a. Assist the donor in completing the donor section of the Federal CCF (Copy 2, Step 5)
    - Record (or instruct the donor to record) donor information indicated on the CCF. The collector must not solicit any donor medical information, and medical information must not be recorded on the Federal CCF or other record maintained or distributed by the collector. See Step 26 regarding a donor-recorded list of medications.
    - Instruct the donor to read the donor certification statement, and to sign and date the certification statement.
      - If the donor refuses to provide their information or to sign the form, make a comment on the Remarks line in Step 2 of the Federal CCF to that effect. This is not considered a refusal to test.
  - b. Complete the collector chain of custody portion in Step 4 on Copy 1 of the Federal CCF.
25. Prepare the specimen package for shipment.
- a. Place the sealed specimen bottles in a leak-resistant container (e.g., plastic bag) including the absorbent material.
  - b. Place the Test Facility Copy (Copy 1) and any collector MFRs in the container with the specimen (i.e., in a compartment separate from the specimen bottles).

**Note:** For a digital Federal CCF, the collector must either (1) include a printed copy of the Federal CCF (for informational purposes only) in the specimen package or (2) apply a label to the outside of the specimen package with the specimen identification number, test facility name and contact information, and collection site name and contact information. Any collector MFRs for the specimen must be included in the package (i.e., in a compartment separate from the specimen tubes) or sent electronically to the laboratory using established procedures (e.g., secure fax, email).

c. Seal the bag so both compartments are sealed.

26. Provide the Donor Copy of the Federal CCF to the donor.

a. Remind the donor that they may list any prescription and over-the-counter medications on a separate sheet or on the back of the donor's copy of the Federal CCF. This information may help the donor to remember what medications they may have taken if they are contacted by the MRO.

**Note:** This information must not be recorded on any other copy of the Federal CCF or other record maintained or distributed by the collector.

27. Inform the donor that they may leave the collection site.

Send the specimen package to the IITF or to the HHS-certified laboratory **within 24 hours after the collection or during the next business day**. Specimens that will not be shipped within 24 hours (e.g., collected on a Friday for shipment on Monday) should be kept in secure refrigerated storage. If the specimen package is not shipped immediately, the collector is responsible for ensuring its security:

- a. For specimens in a sealed specimen package that has not been placed in a shipping container, take necessary steps to prevent tampering or access by unauthorized personnel.
- b. For specimen packages in a sealed shipping container, take necessary steps to protect the container from damage or theft prior to pick-up by the designated delivery service.
- c. If the tamper-evident label/seal is broken on a specimen bottle after the donor leaves the collection site, **the collection must be cancelled**.
  - Notify the agency's designated representative that the label/seal was broken on the specimen bottle, and send all copies of the Federal CCF to the federal agency's designated representative.

29. Distribute the MRO and employer copies of the Federal CCF. **Chapter 5, Section E describes proper distribution of Federal CCF Copies 1–5.**

- a. The collection site and the MRO must coordinate the Federal CCF distribution process to ensure that procedures meet the MRO's and federal agency's requirements.
- b. The collection site or the MRO must maintain the original Copy 2 with the donor's signature (i.e., paper Copy 2 with the donor's wet-ink signature, if signed).

## Chapter 8. Miscellaneous Collection Issues

### A. Direct Observed Collection

See also **Appendix B: Direct Observed Collection Procedure**

A direct observed collection procedure may only be used when:

1. A federal agency has authorized a direct observed collection because a donor's previous drug test result was reported by an MRO as drug positive, adulterated, substituted, invalid without a legitimate medical reason, or cancelled because the split specimen failed to reconfirm the primary specimen results or could not be tested, or
2. At the collection site, an immediate collection of a second urine specimen is required in one of the following situations:
  - a. The temperature of the specimen collected during a routine collection is outside the acceptable temperature range.
  - b. There is an indication that the donor has tampered with the specimen (e.g., abnormal physical characteristic such as unusual color, excessive foaming when shaken, unusual odor).

Before conducting a direct observed collection under Item 2 above, the collector must contact a collection site supervisor for concurrence with the collector's decision for a direct observed collection. The collector must explain to the donor why a direct observed collection is being conducted. If the donor declines to allow a direct observed collection it is considered a refusal to test (see **Chapter 8, Section F**).

The procedure for a direct observed collection is the same as that for a routine collection except an observer watches the donor urinate into the collection container. The observer's gender must be the same as the donor's gender, which is determined by the donor's gender identity. **There are no exceptions to this requirement.** The donor's gender identity may be the same as or different from the donor's sex assigned at birth. At the point in a routine collection where the donor enters the restroom with the collection container (see **Chapter 7, Section C, Step 13**), a direct observed collection includes the following additional steps:

1. The collector informs the donor that the gender of the observer will match the donor's gender, which is determined by the donor's gender identity.
  - a. The collector asks the donor to identify the donor's gender on the Remarks line in Step 2 of the Federal CCF and initial it.
  - b. The donor is provided an observer whose gender matches the donor's gender.
  - c. The collector documents the observer's name and gender on the Remarks line in Step 2 of the Federal CCF.
  - d. If there is no collector of the same gender as the donor's gender, the collector or collection site supervisor must select another individual trained in direct observed

specimen collections. The individual must meet the UrMG qualifications for an observer (see **Chapter 1**).

**Note:** If there is insufficient room on the Remarks line, the collector may send a separate explanatory MFR.

2. The observer enters the restroom with the donor.
3. The observer must directly watch the urine go from the donor's body into the collection container. The use of mirrors or video cameras is not permitted. If the donor fails to follow the observer's instructions related to the direct observed collection, this is considered a refusal to test (see **Chapter 8, Section F**).
4. With regard to chain of custody, the observer must never touch or handle the collection container unless the observer is also serving as the collector.
5. The observer must maintain visual contact with the collection container until the donor hands the container to the collector
6. After the donor has completed urinating into the collection container:
  - a. The donor and observer leave the restroom.
    - The observer must ensure that the employee hands the collection container directly to the collector as soon as the employee has exited the enclosure, or
    - If the same individual serves as both observer and collector, the collector may receive the collection container from the donor while they are both in the restroom.
7. The collector checks the box for an observed collection in Step 2 of the Federal CCF.
8. The collector continues with the routine collection procedures (see **Chapter 7, Section C, Step 14**).

## **B. Monitored Collection**

A monitored collection procedure must be used when:

1. The collection is being conducted in a public restroom (e.g., when the federal agency's designated collection site is not available and there is an immediate need for a collection), or
2. The restroom used for the collection has a water source that cannot be disabled or secured.

If the donor declines to allow a monitored collection when one of the above circumstances has occurred, it is considered a refusal to test (see **Chapter 8, Section F**).

The procedure for a monitored collection is the same as that for a routine collection except a monitor accompanies the donor into the restroom to check for signs that the donor may be tampering with the specimen. At the point in a routine collection where the donor enters the restroom with the collection container (see **Chapter 7, Section C, Step 13**), a monitored collection includes the following additional steps:

1. The monitor accompanies the donor into the restroom and secures the restroom to ensure that no one else can enter during the collection process. The monitor remains in the restroom, but outside the stall, while the donor is providing the specimen.
  - a. The monitor must be the same gender as the donor's gender, unless the monitor is a trained medical professional (e.g., nurse, doctor, physician's assistant, technologist or technician) who is licensed or certified to practice where the collection occurs.
  - b. The monitor may be an individual other than the collector and is not required to be a trained collector.
2. The monitor listens for signs of tampering with the specimen. The monitor must not watch the donor urinate into the specimen container.
3. If there is evidence of specimen tampering, the monitor notifies the collector to immediately begin to collect a second specimen using a direct observed collection procedure (see **Chapter 8, Section A**).
4. With regard to chain of custody, the monitor must never touch or handle the collection container unless the monitor is also serving as the collector.
5. After the donor has completed urinating into the collection container:
  - a. The donor and monitor leave the restroom.
    - The monitor must ensure that the employee hands the collection container directly to the collector as soon as the employee has exited the enclosure, or
    - If the same individual serves as both monitor and collector, the collector may receive the collection container from the donor while they are both in the restroom.
6. The collector provides the name of the monitor (if applicable) on the Remarks line in Step 2 on Copy 1 of the Federal CCF.
7. The collector continues with the routine collection procedures (see **Chapter 7, Section C, Step 14**).

### **C. Inability to Provide a Sufficient Specimen**

If a donor states that they are unable to provide a urine specimen during the collection process, the collector must begin the collection procedure regardless of the reason given. The donor demonstrates their inability to provide a valid specimen when they come out of the restroom with an empty collection container. Immediately begin a second collection using the same procedures, the same collection container (i.e., if no specimen was provided upon the first attempt), and the same Federal CCF. **Appendix D** provides flowcharts for collector actions.

1. If the donor states that they may be able to provide a specimen if given more time:

- a. You must provide a period of up to 3 hours for the donor to attempt to provide a sufficient urine specimen.
- b. Inform the donor that they must remain at the collection site (in the area that you designate) during the wait period. The donor must be monitored to prevent the donor from possibly compromising the collection process.
- c. Offer the donor a reasonable amount of fluid to drink distributed reasonably through a period of up to 3 hours (e.g., an 8 ounce glass of water every 30 minutes, not to exceed 40 ounces over a period of 3 hours) or until the donor has provided a sufficient amount of urine, whichever occurs first. The donor is not required to drink fluids during the waiting period.
- d. Instruct the donor to let you know when they are able to provide a sufficient quantity of specimen. It is recommended that you allow sufficient time to have only one additional attempt rather than having to document several unsuccessful attempts. Be sensitive to how frequently you ask a donor to attempt to provide a specimen.
- e. Record the time of the attempt to provide a sufficient volume of specimen (e.g., on the Remarks line in Step 2 of the Federal CCF).

**Note: The collector must NOT under any circumstances combine urine collected from separate voids to create one specimen of sufficient volume.**

2. If the donor states that they are unable to provide a specimen, or if the donor has not provided sufficient volume of specimen in **three hours** from the time of the donor's first attempt, **discontinue the collection** and:
  - a. Record the reason for not collecting the specimen on the Remarks line and mark the "None Provided" box in Step 2 of the Federal CCF.
  - b. Notify the agency's designated representative for authorization to collect an alternate specimen. The federal agency may provide the collection site with a standard protocol to follow instead of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized by the federal agency, begin the alternate specimen collection procedure.
  - c. Discard the urine collected (if any).
  - d. Provide a copy of the Federal CCF (as described in the Collection Procedure in **Chapter 7, Section C, Step 26**) to the donor. Request that the donor leave the collection site or, if authorized, proceed with the alternate specimen collection.
  - e. Discard Copy 1 of the Federal CCF (no valid specimen was collected).
  - f. Provide a copy of the Federal CCF to the MRO and to the federal agency's designated representative within 24 hours or the next business day (as described in the Collection Procedure in **Chapter 7, Section C, Step 29**).
3. If the donor refuses to attempt to provide a specimen, refuses to provide a second specimen, leaves the collection site before the collection process is completed, refuses a

direct observed collection, or refuses to provide an alternate specimen, these are considered a refusal to test. The collector must follow the procedure in **Chapter 8, Section F**.

#### **D. Donor Conduct**

The collector should pay close attention to the donor's conduct during the entire collection process and take the following actions as necessary:

1. Note any unusual behavior or appearance of the donor in the Remarks line in Step 2 of the Federal CCF.
2. If donor conduct clearly indicates an attempt to tamper with the specimen (e.g., substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute), report a refusal to test immediately to the federal agency in accordance with Section F below.
3. If there is reason to believe the donor may have adulterated or substituted a collected specimen (based on donor actions or an abnormal specimen characteristic including temperature outside of range), complete the collection procedure for the first specimen; perform a second, direct observed collection; and send both specimens to an HHS-certified laboratory (not to an IITF) for testing.
4. Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF for the first specimen to identify this as the first of two specimens collected and the reason why two specimens were collected.
5. Complete the first collection using the procedures in **Chapter 7, Section C**, before initiating the second collection.
6. Begin the second specimen collection using a direct observed collection procedure (see **Chapter 8, Section A**) and a new collection kit (i.e., a new collection container and a new Federal CCF).
7. Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF for the second specimen to indicate why two specimens were collected, including a cross reference to the specimen identification number of the first specimen.

**Note:** The first specimen and its Federal CCF are sent to an HHS-certified laboratory regardless of the specimen volume.

**Note:** If the donor refuses to provide a second specimen or leaves the collection site before the collection process is completed, this is considered a refusal to test (see **Section F** below). **Discard any urine, document the refusal to test on the Federal CCF, and send all copies of the Federal CCF to the federal agency's designated representative.**

8. If the donor fails to arrive at the assigned time within a reasonable time, as determined by the federal agency:
  - a. Contact the federal agency's designated representative to obtain guidance on the action to be taken.

- b. This is considered a refusal to test except for:
- A donor who fails to appear for a pre-employment test; or
  - A donor for a pre-employment test who leaves the collection site before the collection begins (i.e., before the collector provides or the donor selects the collection kit or packaged collection container as described in the **Collection Procedure, Chapter 7, Section C, Step 12**). If the donor for a pre-employment test leaves after that step, before the collection is complete, the collector reports a refusal to test.

## **E. Multiple Collectors for a Specimen Collection**

The procedures for collecting a federal agency drug testing specimen, as required by the HHS Mandatory Guidelines and detailed in this Specimen Collection Handbook, are designed to be performed from start to finish by one trained collector. Collection sites and federal agencies are expected to schedule collections accordingly.

In the rare event when the collector who began a collection cannot complete all steps (e.g., when a collection coincides with a shift change, shy bladder, insufficient specimen), a second trained collector may assume responsibility for the collection.

Prior to changing collectors:

1. The first collector must document their name, the time, and the reason for the change in Step 2 of the Federal CCF. The first collector may, but is not required to, sign in addition to printing their name in Step 2.
2. Before assuming responsibility for the collection, the second collector must:
  - a. Verify the donor's identity with a photo identification (see **Chapter 6**). If the donor requests, you must provide identification (e.g., employee badge, employee list).
  - b. Verify the donor ID number recorded on the Federal CCF.
  - c. Ensure that Step 1 of the Federal CCF is complete.
  - d. Review and verify any information in Step 2 of the CCF recorded by the first collector.

## **F. Refusal to Test**

A federal agency will take adverse action against an employee whose drug test specimen is reported as a refusal to test. The collector reports a "refusal to test" when:

1. The donor fails to appear for a collection within a reasonable time as determined by the federal agency, consistent with federal agency regulations (except for a donor who leaves the collection site before the collection begins for a pre-employment test as noted in **Chapter 8, Section D, Step 8** above).

2. The donor fails to remain at the collection site until the collection is complete (except for a donor who leaves the collection site before the collection begins for a pre-employment test as noted in **Chapter 8, Section D, Step 8** above).
3. The donor fails to cooperate with any part of the testing process (e.g., refuses to provide a specimen, refuses to display the items in their pockets at the beginning of the collection, disrupts the collection process, refuses to wash their hands at the beginning of the collection, or exhibits conduct that clearly indicates an attempt to adulterate, substitute, or dilute the specimen or otherwise prevent collection of a urine specimen),
4. The donor declines to allow a direct observed collection when required, or fails to follow the observer's instructions related to the direct observed collection,
5. The donor declines to allow a monitored collection when required,
6. The donor declines to continue the collection process when their first specimen has insufficient volume,
7. The donor fails or declines to participate in an alternate specimen collection (e.g., oral fluid) as directed by the federal agency or collector,
8. The donor admits to the collector that they have adulterated or substituted their specimen.
9. The donor brings materials to the collection site whose purpose is to adulterate, substitute or dilute their specimen

When reporting a "refusal to test," the collector must:

1. Notify the agency's designated representative by a means (e.g., telephone, secure fax, email) that ensures immediate receipt of the refusal notification,
2. Document the refusal to test on the Federal CCF with appropriate comments, signature, and date in the Remarks line of Step 2 of the Federal CCF, discards any urine, and
3. Send all copies of the Federal CCF to the federal agency's designated representative.

#### **G. Problems with Specimen Bottle Labels/Seals**

If the tamper-evident label/seal does not adhere properly to the specimen bottle (e.g., due to moisture, temperature, specimen tube material) or is accidentally broken or damaged during the collection process:

1. Apply the unacceptable label/seal (i.e., printed with the same identification number as the Federal CCF) to the bottle, and
2. Apply a second, separate tamper-evident seal to seal the specimen bottle.
  - a. Place the additional seal perpendicular to the original label/seal. Position the seal so it does not cover information on the original label/seal and will allow visual assessment of the bottle contents.

- b. Initial and date the second seal.
- c. Ask the donor to initial the second seal.
- d. Provide a comment on the Remarks line in Step 2 of the Federal CCF explaining why the second seal was used.

**Note:** If the donor refuses to initial the second seal, the collector should note this on the Remarks line in Step 2 and continue with the collection process. This is not considered a refusal to test.

## Chapter 9. Collector Errors and Corrective Actions

The Federal CCF is a forensic, legal document and will be part of the litigation package if a specimen comes under legal challenge. Federal agencies will investigate reported collection site deficiencies (e.g., specimens rejected for testing due to collector/collection errors).

The collector should **never** use correction fluid on the Federal CCF and should never overwrite or obscure information recorded or printed on the Federal CCF. Unclear or improper edits to Federal CCF information (e.g., donor ID numbers, signatures) could compromise the legal defensibility of the document.

If the collector makes an error on a Federal CCF, they should:

1. Make a line through the erroneous information, leaving the original information legible,
2. Write the correct information near (e.g., beside or above) the original annotation, and
3. Initial and date the change.

It is acceptable for the collector to line out preprinted information on the Federal CCF that is incorrect or inapplicable (e.g., collection site, MRO, IITF, laboratory, or employer information). The collector must use the procedures described above for changing the information on the form. This may be necessary in the event of unexpected collections (e.g., accident investigation) or when Federal CCFs at the collection site have outdated information.

There are three categories of collector errors:

1. Fatal flaws that result in an HHS-certified IITF or laboratory rejecting a specimen or an MRO canceling a test,
2. Correctable flaws that result in an HHS-certified IITF or laboratory rejecting a specimen or an MRO canceling a test unless the flaw is corrected by an MFR from the collector, and
3. Omissions and discrepancies on the Federal CCF that do not require rejection by the HHS-certified IITF or laboratory or cancellation by the MRO.

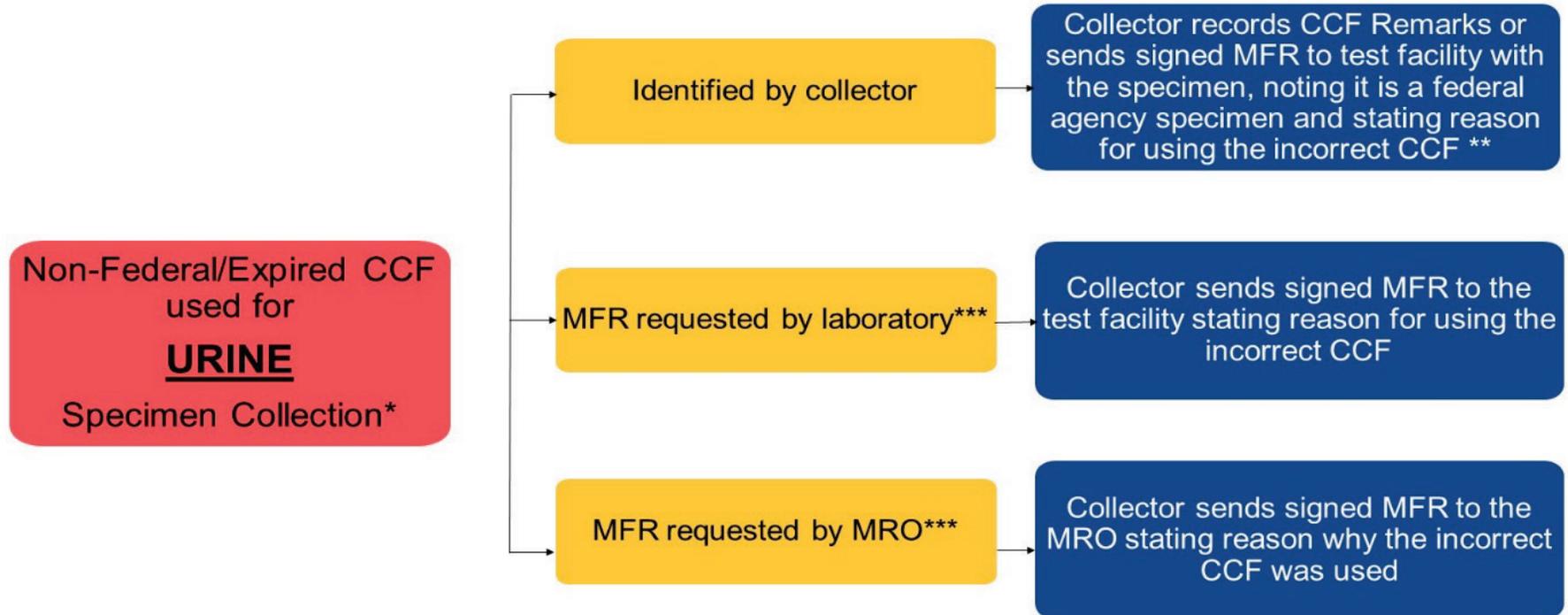
The collector should not access the Federal CCF or the specimen bottles after the package has been sealed in the presence of the donor. If the collector realizes they have made a correctable

flaw or omission after the Federal CCF Copy 1 has been sealed in the specimen package, the collector should proactively send an explanatory MFR to the HHS-certified IITF or laboratory.

***Chapter 5 includes instructions for when an incorrect CCF is used for a federal agency specimen or an incorrect CCF copy is sent with the specimen. See also Appendix A: Federal CCF Decision Trees for Collectors.***

The collector must take **immediate** steps to provide an MFR to the HHS-certified IITF, laboratory, or the MRO when notified of an error. An IITF or laboratory holds specimens for a short time (i.e., a minimum of five business days) after the collector has been notified, before reporting the specimen as rejected for testing and discarding the specimen.

## Appendix A: Federal CCF Decision Trees for Collectors

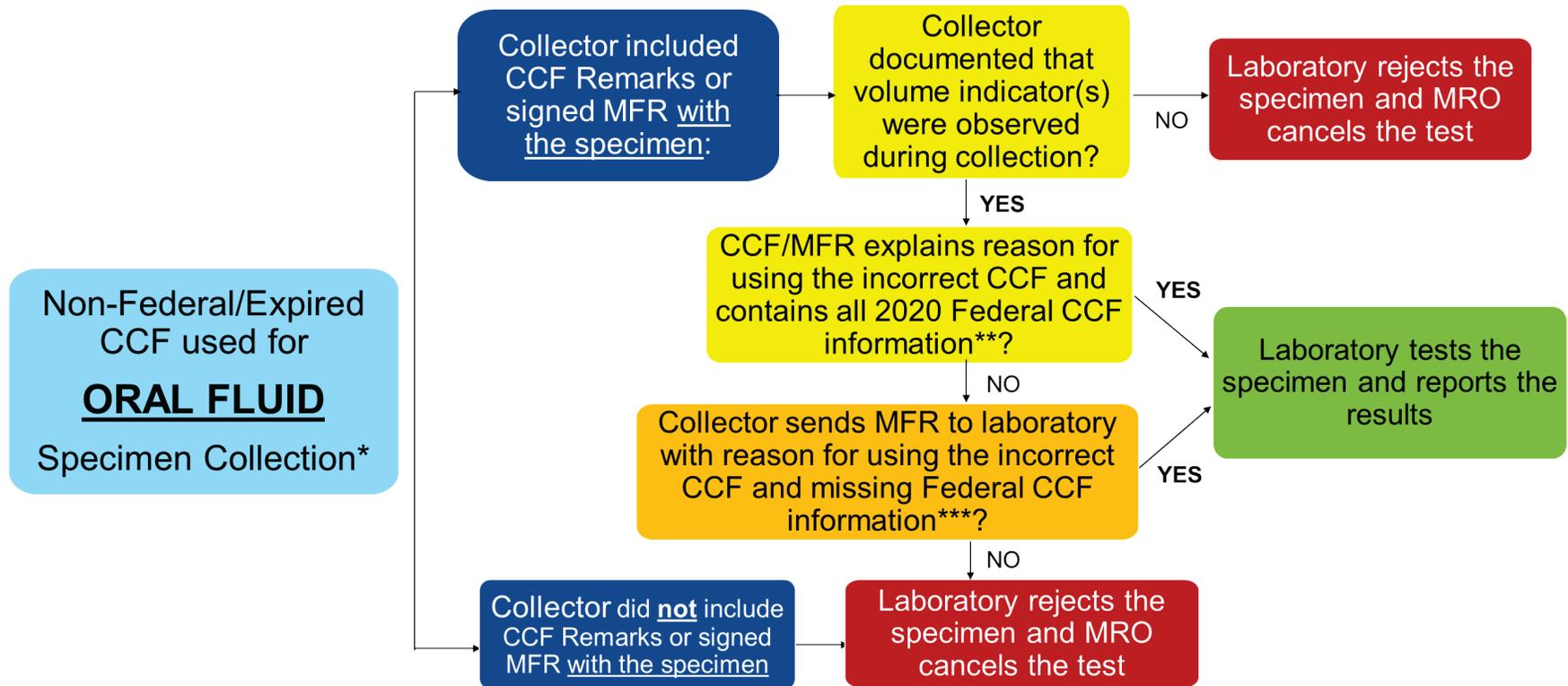


\* The laboratory will reject a specimen that was collected using an ECCF system not approved by SAMHSA for the test facility

\*\* If the non-federal CCF does not include all information required on a Federal CCF, the collector must also include the missing information in the MFR (MFR not required if collector includes the explanatory remarks in Step 2 of the CCF Copy 1).

\*\*\* The collector must take **immediate** steps to provide an MFR when notified. If the collector no longer works at the collection site, the collection site supervisor may sign the MFR.

## Appendix A: Federal CCF Decision Trees for Collectors



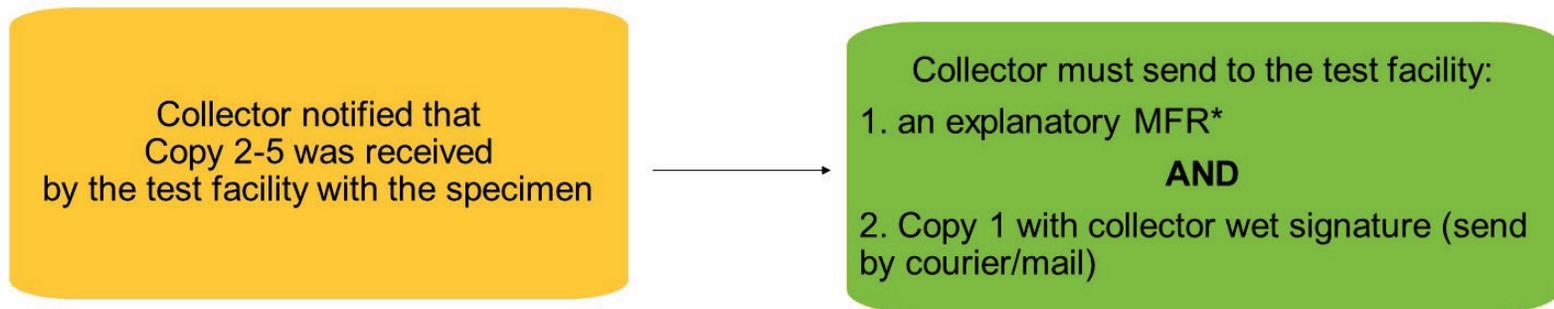
\* The laboratory will reject a specimen that was collected using an ECCF system not approved by SAMHSA for the test facility

\*\* If the non-federal CCF does not include all information required on a Federal CCF, the collector must also include the missing information in the MFR (MFR not required if collector includes the explanatory remarks in Step 2 of the CCF Copy 1).

\*\*\*The collector must take **immediate** steps to provide an MFR when notified. If the collector no longer works at the collection site, the collection site supervisor may sign the MFR.

## Appendix A: Federal CCF Decision Trees for Collectors

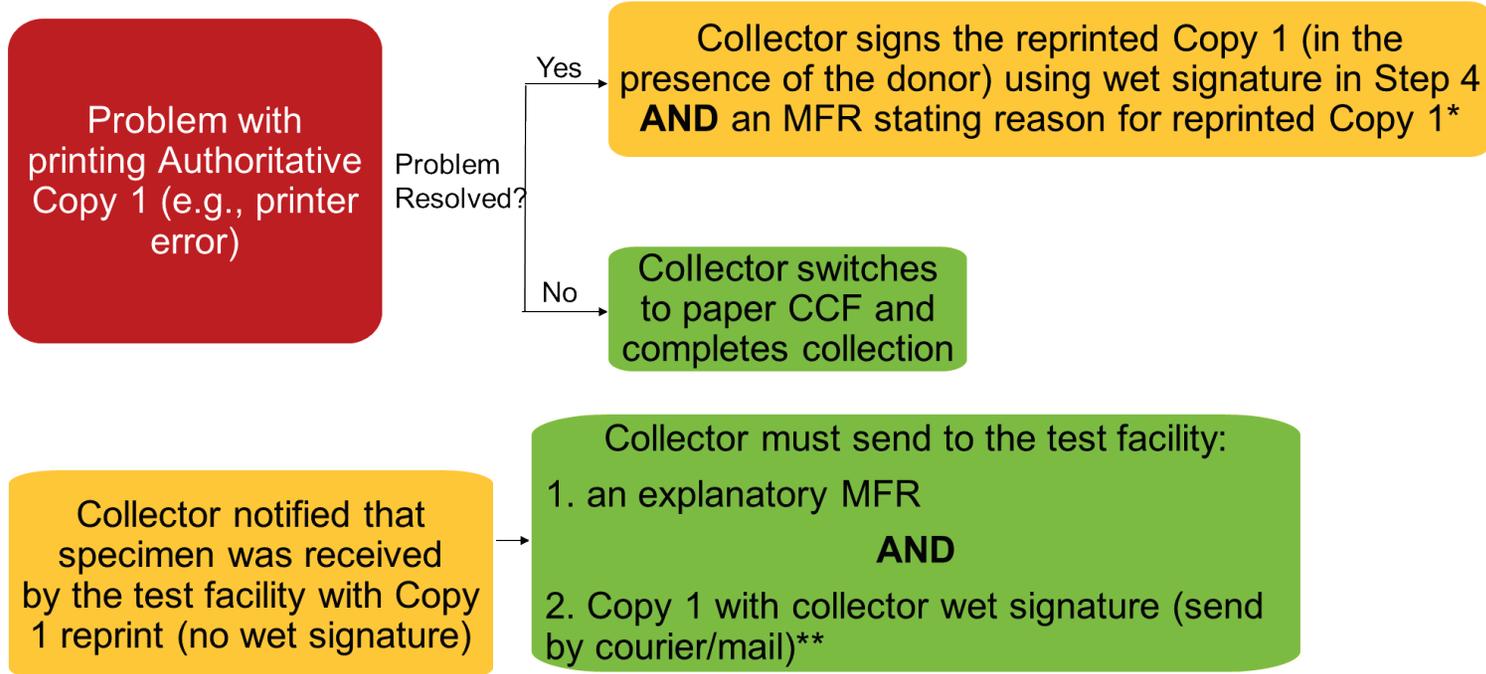
### Incorrect CCF Copy (Copy 2-5) for Urine or Oral Fluid



\*The collector must take **immediate** steps to provide an MFR when notified. If the collector no longer works at the collection site, the collection site supervisor may sign the MFR.

## Appendix A: Federal CCF Decision Trees for Collectors

### Reprint ECCF Copy 1 for Urine or Oral Fluid



\* MFR not required if collector includes the explanatory remarks in Step 2 of the CCF Copy 1.

\*\*The collector must take **immediate** steps to provide an MFR when notified. If the collector no longer works at the collection site, the collection site supervisor may sign the MFR.

## Appendix B: Direct Observed Collection Procedure

### General Note:

For observed collections decided at the collection site - collector contacts a collection site supervisor for concurrence and explains to the donor why a direct observed collection is being conducted. If the donor declines to allow a direct observed collection, it is considered a refusal to test (see Chapter 8, Section B).

1

### Collector informs the donor that the gender of the observer will match the donor's gender (determined by the donor's gender identity).

- Collector asks the donor to identify the donor's gender on the Remarks line in Step 2 of the Federal CCF and initial it.
- Donor is provided an observer (gender matches the donor's gender).
- Collector documents the observer's name and gender on the Remarks line in Step 2 of the Federal CCF.



*If there is no collector of the same gender as the donor to serve as the observer, the collector or collection site supervisor selects another individual trained in direct observed specimen collections.*

2

### Observer enters the restroom with the donor.

- Observer must directly watch the urine go from the donor's body into the collection container.

*If the donor fails to follow the observer's instructions related to the direct observed collection, this is considered a refusal to test (see Chapter 8, Section B).*



- Observer must never touch or handle the collection container unless the observer is also the collector.
- Observer must maintain visual contact with the collection container until the donor hands the container to the collector

3

### After the donor has completed urinating into the collection container:

- Donor and observer leave the restroom and the donor hands the collection container directly to the collector **OR**
- If the same individual serves as both observer and collector, the collector may receive the collection container from the donor while they are both in the restroom.



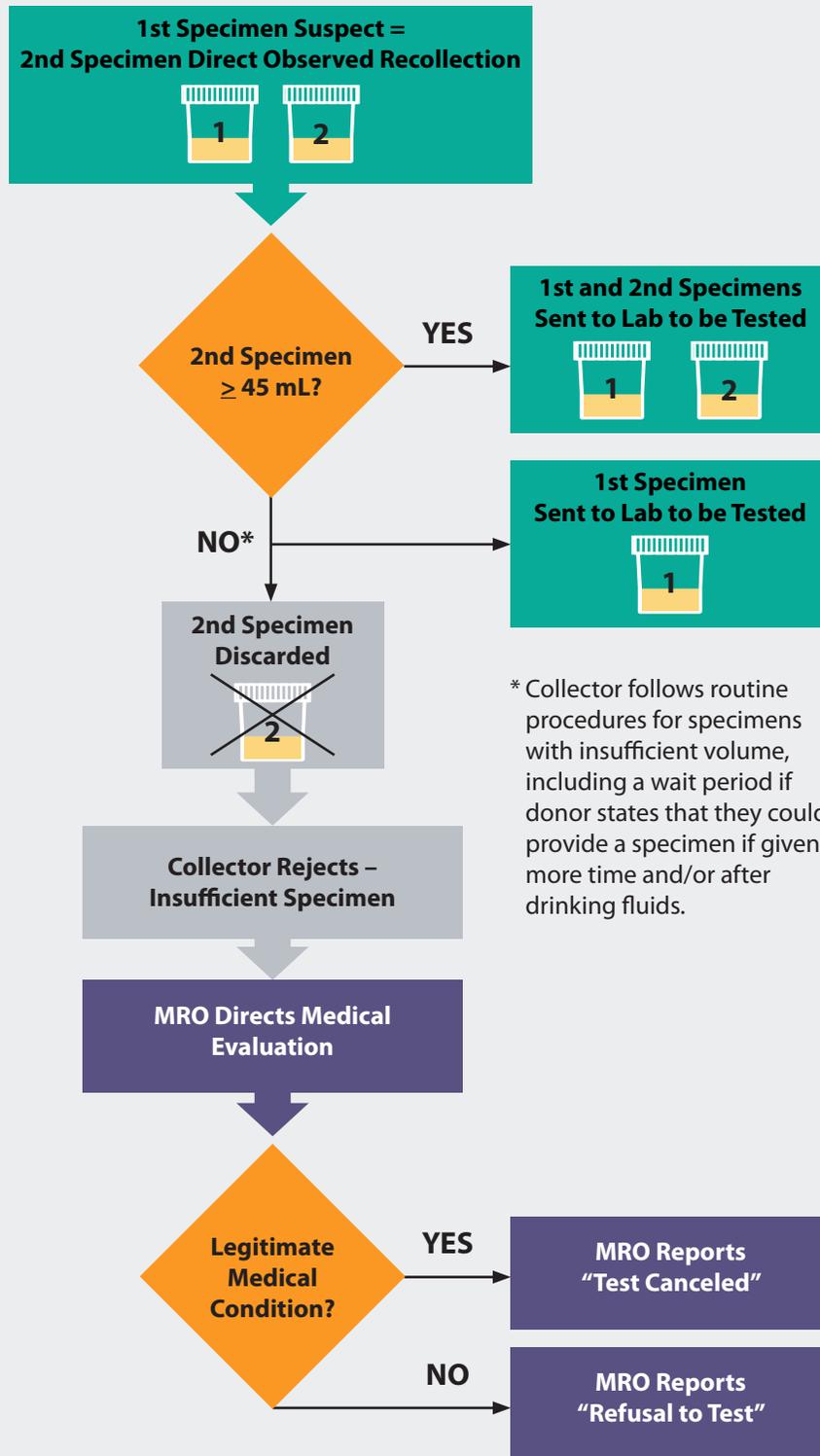
4

### Collector checks the box for an observed collection in Step 2 of the Federal CCF.

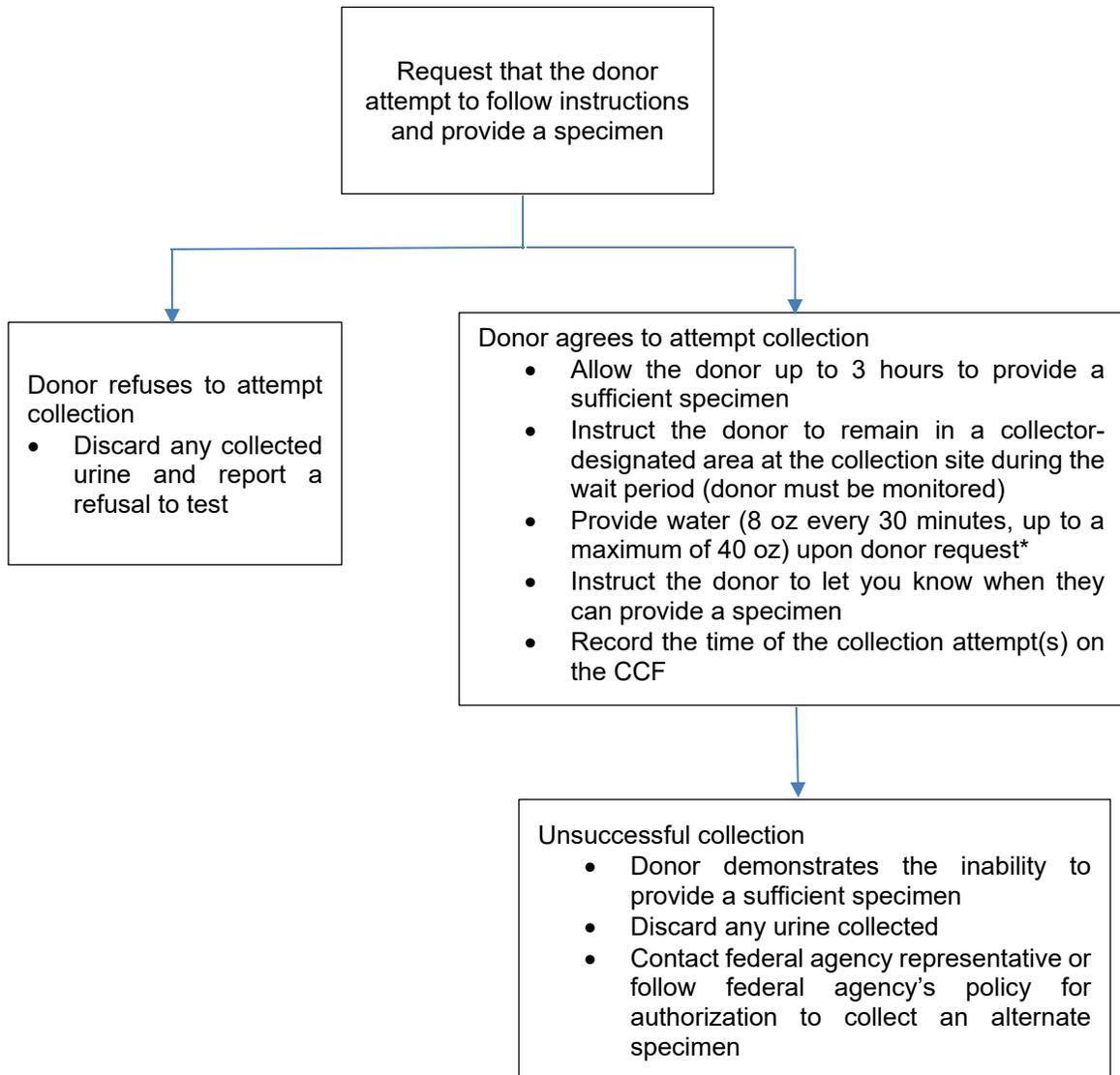
- Collector provides the reason for an observed collection on the Remarks line in Step 2 of the Federal CCF.
- Collector continues with the routine collection procedures (see Chapter 7, Section C, Step 13).



## Appendix C: Two Specimens from the Same Collection Event



## Appendix D: Insufficient Specimen



\*Donor is not required to drink any fluids.